K081821

SECTION 5: 510(k) SUMMARY

SEP - 2 2008

In accordance with the requirements of 21 CFR 807.92(c) Global Pathogen Solutions Inc. (hereafter "GPS") has prepared this 510(k) Summary to provide information supporting the substantial equivalence of the D.A.R.T. (stun gun Dart-Acquiring and Removal Tool) Pro Kit, comprised of the reusable D.A.R.T. Pro Handle and the single-use only X-TRACTOR Tip.

General Information:

Date of Summary Preparation:	June 26, 2008
Name and Address of Manufacturer:	Global Pathogen Solutions Inc. 9515 312th Ave Camas, Washington 98607
Contact Person:	Carson Linker President/CEO Phone: (503) 679-7612
Trade Name:	D.A.R.T. Pro Kit (D.A.R.T. Pro Handle and X-TRACTOR Tip)
Common Name:	Sharps Container
Device Classification:	Hypodermic Single Lumen Needle
Classification Panel:	General Hospital
CFR Reference:	880.5570
Product Code:	MMK
Device Class:	Class II

Indications for Use: The D.A.R.T. Pro Handle and X-TRACTOR Tip are solely intended for use in the acquisition, removal and storage of darts projected from stun guns and lodged in human tissue and/or clothing. The device is not intended for use as a medical sharps container.

Predicate Devices: The D.A.R.T. Pro Kit, including the D.A.R.T. Pro Handle and the X-TRACTOR Tip, is substantially equivalent to the following legally marketed predicate devices in consideration of the limited and specific use of the device for stun gun dart removal:

- Sterilogic Waste Systems, Inc. SteriSharp™ Sharps Disposal Containers (K020664)

- Dura-Vac Sharps Safe (K955514)
- MedPort, LLC On the Go Sharps Transport and Disposal with Safe Lock™ (K070577)

Device Description: The reusable D.A.R.T. Pro Handle and detachable, single-use only X-TRACTOR Tip (including a safety cap) comprise the two components of the device. Each of these components is described generally below.

- **D.A.R.T. Pro Handle:** A reusable handle component that is uniquely designed for the secure attachment (and removal post-use) of the X-TRACTOR Tip. The D.A.R.T. Pro Handle allows the user to hold, control and position the assembled product as required for stun gun dart acquisition and removal within the X-TRACTOR Tip. The D.A.R.T. Pro Handle includes a switch at the top of the handle to activate an internal LED light source to illuminate the X-TRACTOR Tip to ease device use in darkened environments. The LED light requires only a standard 9-volt battery, which the user can easily replace as needed.

- **X-TRACTOR Tip:** A single-use, detachable stun gun dart containment tip specifically designed to securely house up to two stun gun darts. In use, the X-TRACTOR Tip is placed over the stun gun dart and advanced to lock the dart into a sliding tip collet. The D.A.R.T. Pro Handle is then pulled to remove the dart. The external button on the tip collet is then pressed to slide the tip collet and secure the removed dart within the X-TRACTOR Tip. Following removal of up to two stun gun darts, the safety cap is press-fit over the X-TRACTOR Tip to securely house the darts within the X-TRACTOR Tip. Once placed, the safety cap cannot be removed from the X-TRACTOR Tip. The capped X-TRACTOR Tip is then removed from the D.A.R.T. Pro Handle, placed within a zip-seal bag, and the zip-seal bag appropriately identified for provision to law enforcement personnel.

Device Testing: Performance testing of the D.A.R.T. Pro Kit included the following sharps container tests conducted on the capped X-TRACTOR Tip, which houses the removed stun gun darts.

Test	Standard	Description	Results
Puncture	Health Devices 22 ASTM F04.33.01	Sharps (needle) penetration force	Pass
Leak Resistance	Health Devices 22	24 hours filled with water	Pass
Vibration	49 CFR 178.608	1 hour repetitive bounce	Pass
Free Fall Drop	49 CFR 178.603	5 drops from 3.9 feet	Pass
Stacking	49 CFR 178.606	24 hours under 16.6 lbs	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carson Linker
President/ Chief Executive Officer
Global Pathogen Solutions, Incorporated
9515 N.E.312th Avenue
Camas, Washington 98607

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Re: K081821
Trade/Device Name: D.A.R.T. (Stun Gun Dart-Acquiring and Removal Tool) Pro Kit, Including the D.A.R.T. Pro Handle and X-TRACTOR Tip
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: August 20, 2008
Received: August 22, 2008

Dear Mr. Linker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

JH Samuelson, MD for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K081821

Device Name: D.A.R.T. (stun gun Dart-Acquiring and Removal Tool) Pro Kit, including the D.A.R.T. Pro Handle and X-TRACTOR Tip

Indications for Use: The D.A.R.T. Pro Handle and X-TRACTOR Tip are solely intended for use in the acquisition, removal and storage of darts projected from stun guns and lodged in human tissue and/or clothing. The device is not intended for use as a medical sharps container.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081821

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